

510(K) Summary: BEACON™ Stabilization System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

Contact: Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory

DEC 13 2007

Device Name: BEACON™ Stabilization System

Classification: Per 21 CFR as follows:
§888.3050 Spinal Interlaminar Fixation Orthosis
§888.3060 Spinal Intervertebral Body Fixation Orthosis
§888.3070 Pedicle Screw Spinal System
§888.3070 Spondylolisthesis Spinal Fixation Device System
Product Codes MNH, MNI, KWQ, KWP, NKB.
Regulatory Class II and III, Panel Code 87.

Predicate(s): Globus Medical REVERE Stabilization System
K061202, SE date July 20, 2006
Product Codes MNH, MNI, KWQ, KWP, NKB.
Regulatory Class II and III, Panel Code 87.

Device Description:

The BEACON™ Stabilization System consists of rods, posted screws, reduction screws, clamps, connectors and associated manual surgical instruments. Screws and rods are available in a variety of sizes to accommodate individual patient anatomy. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Screws, clamps, and rods may be used anteriorly or posteriorly. Connectors are intended for posterior use only. Preassembled clamps are used to connect screws to the rod.

The most common use of this screw and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws. The most common use of this screw and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via screws through an appropriate size staple.

The rods are composed of titanium alloy, or commercially pure titanium, as specified in ASTM F136, F1295, and F67. All other BEACON™ implants are composed of titanium alloy, as specified in ASTM F136, and F1295. Due to the risk of galvanic corrosion following implantation, titanium or titanium alloy implants should not be connected to stainless steel implants.

Intended Use:

The BEACON™ Stabilization System, when used as posterior pedicle screw systems, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the BEACON™ Stabilization System is intended for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as a posterior non-pedicle screw fixation system (using REVERE™ hooks), the BEACON™ Stabilization System is intended for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis, Scheuermann's disease), fracture, pseudoarthrosis, tumor resection, and/or failed previous fusion. Overall levels of fixation are T1-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the BEACON™ Stabilization System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Basis of Substantial Equivalence:

The BEACON™ Stabilization System implants are similar to the predicate REVERE™ Stabilization System (K061202) implants system with respect to technical characteristics, performance, and intended use. Mechanical testing in accordance with the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004 is presented.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 13 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Globus Medical Inc.
% Kelly J. Baker, Ph.D.
Director, Clinical Affairs & Regulatory
2560 General Armistead Ave.
Audubon, PA 19403

Re: K073172
Trade/Device Name: BEACON™ Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWQ, MNH, MNI
Dated: November 12, 2007
Received: November 13, 2007

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number:

K073172

Device Name:

BEACON™ Stabilization System

INDICATIONS:

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When used as an anterolateral thoracolumbar system, the BEACON™ Stabilization System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

Prescription Use X
(Per 21 CFR §801.109)

OR

Over-The-Counter Use

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

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